

Remarks

This Amendment is responsive to the Office Action mailed September 22, 2000 (Paper No. 7). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-38 were pending. Claims 1-38 stand or stood rejected.

Claim 25 and 37-38 have been canceled without prejudice or disclaimer of the subject matter therein. Moreover, Applicant reserves the right to prosecute, in one or more patent applications, the canceled claim, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification.

Claims 1-2, 8-9, 12, 17 and 21 have been amended to more particularly and distinctly define the invention. No new matter is added.

Support

Support for the amendments to the claims is either apparent or as set forth herein. Specifically, support for the recitation "consisting of a single layer of a filmogenic polymer" may be found in the specification at, for example, page 7, lines 3-13. No new matter is added.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-38 stand or stood rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Examiner asserts that

[r]ecitation of "reversing erectile dysfunction" is indefinite. It is submitted that this term implies that all blood vessels of the penis dilate as a result of application of the instant composition to the penis, while it is the position of the examiner that some blood vessels may remain unaffected. The examiner recommends "treating erectile dysfunction" to overcome this rejection.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033

(Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 5 and 21 recite the broad recitation “a vasodilator”, and the claim also recite a smooth muscle relaxant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, an alpha-blocker and a calcium channel blocker which are narrower statements of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation “an aliphatic alcohol”, and the claim also recites a fatty acid ester of an aliphatic alcohol and an aliphatic alcohol ether of a glycol, which are narrower statements of the range/limitation.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the first two assertions of this rejection. With respect to the third assertion, that an aliphatic alcohol encompasses an aliphatic alcohol ether of a glycol and a fatty acid ester of an aliphatic alcohol, Applicants respectfully traverse. Applicants respectfully note that an aliphatic alcohol is a class of compounds having a formula R-OH, wherein R is an aliphatic chain. Contrarily, a fatty acid ester of an aliphatic alcohol is a class of compounds having a formula R-OCOR₁, wherein R₁ is a fatty acid and R is an aliphatic chain. Furthermore, an aliphatic alcohol ether of a glycol is a class of compounds having a formula R-

0-R2, wherein R is an aliphatic chain and R2 is a glycol moiety. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 9, 12, 37 and 38 stand or stood rejected under 35 U.S.C. § 112, second paragraph, as indefinite for including a trademark. Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection.

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Examiner asserts that

[r]ecitation of “derivative” in claim 8 is indefinite since it is not specified what the derivative is. Derivatives of compounds are considered “so indefinite as to be meaningless” since they “cover such a large number of compounds, whose structures are not defined, that the specification does not support the claims” (Petrolite v. Watson, Comr. Pats. 113 USPQ 248, 1957). In the instant application, the specification does mention a cyclohexanol derivative but does not define what derivatives the claim is intended to encompass.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1-8, 13, 18-24, 27 and 36 stand rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,007, 836 (Denzer). Specifically, the Examiner asserts that

‘836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract, C7, L38-C8, L5; C8, L53-C9, L6). ‘836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The composition of ‘836 produce an erection “on demand, immediately before sexual intercourse” and are therefore thought to be released in less than one hour.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-8, 10-11, 13, 17-27, 29 and 34-36 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,007,836 (Denzer). Specifically, the Examiner asserts that

‘836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolaminer and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). ‘836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. The compositions of ‘836 produce an erection “on demand, immediately before sexual intercourse” and are therefore thought to be released in less than one hour. ‘836 does not state whether the penile surface requires pre-wetting. It is submitted that since it not say that wetting the surface is required, no pre-wetting is necessary. It is also submitted that the pre-wetting the surface would be obvious to one skilled in the art at the time the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum.

Without conceding the validity of this rejection, applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-8, 10-11, 13-14, 17-30, 34-36 stand rejected under 35 U.S.C. § 103 as unpatentable over a combination of Denzer and U.S. Patent No. 4,696,821 (Belsole). Specifically, the Examiner asserts that

‘836 is relied upon for all that it teaches as stated previously.

‘821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. ‘821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since ‘821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of ‘821 is outside the instant ranges, applicants are requested to submit evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the

time of the invention to adjust the amount of plasticizer in the composition to increase or decrease the flexibility of the film.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

Without conceding the validity of this rejection, applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-8, 10-11, 13, 15-27, 29 and 31-36 stand rejected under 35 U.S.C. § 103 as unpatentable over a combination of Denzer and FR 2710649 (Postaire). Specifically, the Examiner asserts that

'836 is relied upon for all that it teaches as stated previously.

'649 is relied upon for teaching transdermal films formulated as biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.

Without conceding the validity of this rejection, applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

FEE DEFICIENCY

☒ This Paper is believed timely filed with a one (1) month extension of time. If an additional extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an additional extension of time; The Commissioner is hereby authorized to charge the fee for any such additional extension to Deposit Account No. 04-0480.

and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

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Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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